Revolutionary Medical Devices, Inc.

SuperNO$_2$VA™

SUPERNO$_2$VA™ TIPS FROM REVOLUTIONARY MEDICAL DEVICES, INC. (RMD)

This document serves as an adjunct to the SuperNO$_2$VA™ training video provided by RMD. It is meant to be supplementary in nature, and does not replace formal in-servicing by a trained sales representative or clinical specialist from RMD. If you have any questions, please do not hesitate to email info@rmdevices.com or call 800-224-8194.

The goal of the SuperNO$_2$VA™ device is to generate a positive nasal pressure that is capable of maintaining upper airway patency, deliver PEEP and ventilatory support, and provide rescue nasal ventilation during surgical procedures under anesthesia and throughout the peri-operative period. In order to generate a positive pressure, it is important to begin with a very basic principle:

Pressure = Flow x Resistance

By manipulating flow and resistance, these tips will help the clinician understand how to generate positive pressure and use the SuperNO$_2$VA™ to its fullest capacity. There are three basic steps to maximize success: create a tight seal, begin with high fresh gas flow, and set the APL valve closed or at least to 10-15 cmH_2O.

*** *Start tight, start high, and start closed*, then titrate and adjust thereafter. After reading this list of best practices, a helpful algorithm is provided to help troubleshoot during clinical procedures.

1. SEAL *(START TIGHT)*

First, let us begin with the SuperNO$_2$VA™'s seal to maximize the resistance end of the equation. It was ergonomically designed to create an airtight seal around the patient's nose. When fixed properly, very high pressures can be generated within the SuperNO$_2$VA™ nasal chamber with no leak. If you can minimize leak around the device, you will inherently minimize loss of resistance in the system. When first using the device, our recommendation is that you affix the device *tightly* to the patient's face to ensure that there won't be a leak. Once you gain comfort with the SuperNO$_2$VA™, or if there is no appreciable leak around the device, it can be loosened as you see fit. If you are unsure whether there is a leak coming from around the mask, apply direct pressure to the SuperNO$_2$VA™ into the face to create an airtight seal. Remember that the nasal bridge, bilateral zygoma, and maxilla are all bony, rigid structures and direct pressure onto these bony prominences will create a mask seal without disadvantageous movement of the face or neck.

2. FLOW *(START HIGH)*

Positive pressure cannot be generated without a flow source. If we consider the patient and the flow source (anesthesia machine, hyperinflation bag with oxygen source, etc.) as a closed system, then as long as the volume of fresh gas flow entering the system is greater than the volume of gas lost to leak, pressure will build within that system. To achieve this, one must completely fill the reservoir bag while simultaneously minimizing leak (from around the mask, or the mouth). In order to do this quickly and effectively, we recommend starting with high fresh gas flows (> 10 L/min) at the beginning of the case. You should recognize the reservoir bag filling and, as long as the upper airway is patent and the patient is breathing spontaneously, the reservoir bag should intermittently deflate with successful inhalation. With high fresh gas flows, small leaks in the system (from around the device or from the mouth) may be overcome while maintaining positive pressure. Keep in mind that with high fresh gas flows, it may become difficult to monitor end-tidal carbon dioxide because of washout. By minimizing the leaks from the system, you will be able to decrease fresh gas flows, which will result in better $EtCO_2$ monitoring (see supplemental tips on monitoring $EtCO_2$ below).

3. RESISTANCE *(START CLOSED)*

Given an airtight seal with the SuperNO$_2$VA™ device, and adequate fresh gas flows entering the system, the level of positive pressure achieved within the system is controlled with resistance via the APL valve on either the anesthesia machine or hyperinflation bag. For the majority of patients, 5-10 cmH_2O is adequate to maintain upper airway patency, keeping in mind that certain patients may require more. We recommend starting with the APL valve closed to 10-15 cmH_2O on the anesthesia machine and completely closed on the hyperinflation bag included in the SuperNO$_2$VA™ Satellite Set. Remember that this valve is titratable and that it can be opened to decrease pressure based on patient requirements. Starting high, however, will better ensure quicker pressurization at the start of the case and sooner identify system leaks to be addressed (from around the device or the mouth).

Caution: the hyperinflation bag included in the SuperNO$_2$VA™ Satellite Set is designed with a pressure bleed to prevent over-pressurization. If you are using a different hyperinflation bag or Jackson-Rees device, a completely closed APL valve may lead to over-pressurization and patient injury.

SUPPLEMENTAL TIPS FROM RMD:

1. ADDRESSING ORAL LEAK

Given an adequately tight seal around the SuperNO$_2$VA™ device, the most common place for a leak in the system is via the mouth. There are several ways in which to minimize the leak from the mouth; keeping in mind that complete resolution of the mouth leak is not always necessary (as long as fresh gas flow volume is higher than the leak volume):

A. Head Position: Although counter-intuitive at first, a neutral or slightly flexed head position is advantageous during nasal positive pressure generation. When the head is slightly flexed, the tongue is forced into the hard palate, occluding the oral cavity and allowing for positive pressure to build behind the soft palate and oropharynx. We recommend only 10-15 degrees flexion, as extreme flexion may occlude the oropharynx and cause complete upper airway obstruction.

B. Manual Closure of the Mouth: Simple manual closure of the lips and mouth will minimize oral leak.
C. Sub-mental Pressure: In the event that simple lip closure results in continued leak from the mouth or if the external mouth cannot be closed (bite block in place, endoscope or probe in the mouth, etc.), the oral cavity can be occluded internally. With your fingers, feel for the soft tissue in the sub-mental space, the base of the tongue. Using firm pressure, drive the tongue cephalad and anterior towards the hard palate. The tongue, driven against the hard palate, will seal the oral cavity. This is useful despite presence of an endoscope, bronchoscope, or TEE probe because the tongue will seal around the scope and into the hard palate.

Although the goal is to provide nasal positive pressure with a hands-free technique, some patients may require continued or intermittent manual assistance to minimize leak and maintain positive pressure throughout the procedure.

2. MONITORING END-TIDAL CARBON DIOXIDE

While the SuperNO$_2$VA™ device does not have direct capnography monitoring abilities, end-tidal carbon dioxide can still be monitored in normal fashion from the standard anesthesia circuit. Given high fresh gas flows, positive pressure within the mask, and potential leak or exhalation from the mouth, capnography may be difficult to monitor via the nasal mask due to gas washout. Both lowering fresh gas flow and minimizing mouth leak will improve capnography capture.

If EtCO_2 is not present, there are two other monitors that are useful to ensure successful ventilation. First, the reservoir bag should intermittently deflate or depressurize during inhalation as the patient pulls volume from the system into the lungs. The presence of intermittent depressurization is confirmatory of successful inhalation. Additionally, if there is continuous pressure waveform monitoring (as seen with all ventilators or anesthesia machines), you will appreciate intermittent depressurization during successful inhalation.

3. USING THE SUPPLEMENTAL O_2 PORT

Certain procedures require complete patency of the oral cavity, which inherently causes a large gas leak from the mouth (e.g. bronchoscopy, laryngoscopy, open airway laryngeal surgery). In these cases it is impossible to occlude the oral cavity. Using the auxiliary oxygen port on the SuperNO$_2$VA™ connected to any oxygen source via standard oxygen tubing, an additional 10-15 L/min of oxygen flow can be delivered through the SuperNO$_2$VA™. At this point nearly 30 L/min can be achieved, which is transmitted via the nasopharynx directly towards the glottis. This extra flow is considerably valuable in maintaining oxygenation during spontaneous respiration and periods of apnea. RMD recommends using the additional flow during all of these aforementioned procedures or during any other procedure where mouth leak is preventing adequate pressurization of the system.

SUPERNO$_2$VA™ TROUBLESHOOTING ALGORITHM